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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 09/692,257
Filing Date: October 19, 2000
Appellant(s): MILLER ET AL.

Gautam Prakash
Holly L. Prutz
David R.Marsh
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 5/11/07 appealing from the Office action mailed 11/13/06.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The following are the related appeals, interferences, and judicial proceedings known to the examiner, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

SN: 09/619643, SN: 09/684,016, SN: 10/361,942, SN: 09/199,129, SN: 09/920,953, SN: 09/663,423, SN: 09/237,183 and SN: 10/437,963.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 101***

1. Claims 1 and 8-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

The claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any polynucleotide. The specification discloses many potential uses for the polynucleotide including identifying promoters involved in gene regulation (pg. 37, lines 13-27 to pg. 38, lines 1-6), determining whether a plant contains a mutation (pg. 14, lines 10-27 to pg. 15, lines 1-12 and pg. 38, lines 7-27), and acting as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (pg. 46, lines 4-46). These are non-specific uses that are applicable to polynucleotides in general and not particular or specific to the polynucleotide claimed. Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the promoters, mutations, or genes that are to be identified as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, mutations, and

genes does not constitute a specific and substantial utility. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the polynucleotides such that another non-asserted utility would be well established for the compounds.

***Claim Rejections - 35 USC § 112, first paragraph (Enablement)***

2. Claims 1 and 8-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a "specific or substantial" asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

**(10) Response to Argument**

Appellant's arguments drawn to the above rejection have been fully reviewed and considered. However, they are not found persuasive for the reasons that follow. The paragraph numbers used in the response to argument section follow those used in the Brief.

**7-A.** - Appellant summarizes that the specification provides a specific, substantial, and well-established utility for the nucleic acid SEQ ID NO: 1. Appellants have provided several substantial and well-established utilities for SEQ ID NO: 1, and these utilities are specific *i.e.* they are not applicable to any general nucleic acid sequence. Appellant further alleges that because the claimed nucleic acid molecules provide at least these benefits, this satisfy the utility requirement of 35 USC 101. Appellant alleges that because the specification teaches how to

make and use the claimed nucleic acid molecules for the disclosed utilities, the enablement requirement of 35 USC 112 has been met.

In response, it is noted that the specification at page 15, lines 1-12 provides a general definition of what constitutes a polymorphism and general means for detecting or determining the existence of polymorphisms as known in the art. However, no disclosure of any polymorphisms is provided that is specific to the nucleic acid molecule (SEQ ID NO: 1) recited in the claims 1 and 8-13. To the contrary, according to Appellant's specification (e.g., page 14, lines 10-17 to page 15, lines 1-12), "the group of marker nucleic acid molecules which specifically hybridize to a nucleic acid molecule consisting of the nucleic acid sequence selected from the group consisting of SEQ ID NO: 1 through SEQ IDN NO: 14882 or complements thereof...", the specification does not explain why any of the these nucleic acid molecules disclosed in the specification, or more specifically a nucleic acid molecule comprising the sequence of SEQ ID NO: 1 would in fact be useful in detecting a polymorphism or whether the claimed nucleic acid molecule can, in fact, be used to detect any polymorphism, whatsoever. The specification generally teaches using the claimed nucleic acid molecules to identify a polymorphism, but fails to teach that a polymorphism would in fact be detected.

Further, the specification provides no information with regards to the genes represented by the nucleic acid, and accordingly, detecting the presence or absence of a polymorphism provides the barest information in regards to genetic heritage or association to a disease or condition. There are a myriad of polymorphisms that are known to occur in nucleic acid molecules in plants, etc, both of the silent type and those that result in significant phenotypic effects. However, without evidence characterizing those polymorphisms or information

concerning the gene(s) represented by the claimed nucleic acid molecule(s) which may or may not comprises the polymorphisms or some type of association of the polymorphism with a genetic trait, disease or condition, nothing is gained and no substantial, specific or patentable utility is presented. Further research would be required to determine what said detection of polymorphism indicates. This need for further research also supports the lack of currently available form of utility.

**7-B**. - Appellant summarizes the lack of utility rejection and alleges that the analysis made by the Examiner misstates the nature of the asserted uses, ignores disclosed utilities and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson.* Appellant states that the invention need only provide one identifiable benefit to satisfy 35 USC 101. In response, the Examiner maintains that Appellant has *not provided a single identifiable benefit* that satisfies 35 USC 101 because the alleged utilities recited in the specification are general utilities and are not considered to be specific or substantial in view of the limited information provided in the specification. No plant traits are attributed to any SEQ ID NOs, no complete gene sequence is discussed for any SEQ ID NO, especially the claimed sequence of SEQ ID NO:1. No DNA maps or chromosomal locations are identified, no polymorphism is identified and the specification does not disclose how a polymorphism would be recognized by those of ordinary skill in the art given the incomplete sequences disclosed. The specification only provides general uses of the claimed nucleic acid molecules with no evidence or factual experimentation to substantiate those uses. These arguments are an allegation without arguing the specifics of the rejection and are thus non-persuasive.

Appellant summarizes a test for utility directed to an "identifiable benefit". Appellant argues that identifiable benefits are provided in the specification, for example, use to identify the presence or absence or a polymorphism, and use as a hybridization probe for expression profiling. Appellant asserts that either of these utilities described alone is enough to satisfy section 101.

In response, the Examiner maintains that none of these uses, e.g., to identify the presence or absence of a polymorphism, and use as a hybridization probe for expression profiling, is specific to any of the sequences found in one or more of SEQ ID NO: 1 through SEQ ID NO: 14882 as recited in the instant application. The utilities are merely generic in nature. The specification has not established if the claimed nucleic acid molecule or any of other sequences recited in the application is a coding nucleic acid (thus expressed, and could be detected in an expression assay) or a regulatory element. All discussion of polymorphisms in the specification is generic in nature and no evidence is provided or any polymorphisms identified which establishes that polymorphisms for the claimed nucleic acid molecules in fact exist. The specification lacks disclosure of any specific or substantial phenotypic association or even predisposition regarding any claimed nucleic acid. This lack of such association can only be remedied, if such association with any phenotype even exists for the claimed nucleic acids, by further research. The specification teaches a marker utility for the instant invention and procedures for marker usage which includes expression profiling but again this discussion is generic in nature without any association or even vague connection to any of the sequences recited in the specification or claimed in claims 1 and 8-13. Thus, these generic procedural guidelines lack specificity as well as substantiality regarding the utility of the instantly claimed

invention, which is directed to a particular nucleic acid molecule. Appellant's arguments are non-persuasive.

**7C.** - Appellant asserts that the enablement of the claimed nucleic acid molecules has been challenged. Appellant argues that the rejection is erroneous and has been overcome by the arguments states above regarding the utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention".

In response, it is noted that the enablement rejection is based on the fact that no patentable utility has been set forth for the claimed invention and thus, one would not know how to use the claimed invention based on the disclosure of the specification. This rejection is simply a corollary of the finding of lack of utility as discussed above. All of the arguments set forth by the Examiner for a lack of utility are applied here for lack of enablement. The Examiner again asserts that since no specific, substantial or well-established utility has been set forth by Appellant, one skilled in the art would not know how to make or use the invention. Accordingly, Appellant's arguments are not persuasive.

**7D.** – Appellant asserts that the claimed nucleic acids satisfy the written description requirement under 35 U.S.C. 112.

Upon reconsideration, the written description over claim 1 is withdrawn.

For the above reasons, it is believed that the rejections under 35 U.S.C. 101 and 35 USC § 112, first paragraph (Enablement) over claims 1 and 8-13 should be sustained.

Respectfully submitted

Joyce Tung
Examiner
Art Unit 1637

September 10, 2007

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